Clinical trial results:
A Phase 2b Multicenter, Randomized, Placebo-controlled, Dose-ranging Study to Evaluate the Efficacy and Safety of JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis

Summary

EudraCT number	2021-003700-41
Trial protocol	ES
Global end of trial date	16 December 2022

Results information

Result version number	v1 (current)
This version publication date	30 December 2023
First version publication date	30 December 2023

Trial information

Trial identification

Sponsor protocol code	77242113PSO2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05223868
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 Route 202, South Raritan, New Jersey, United States, 08869
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 January 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the dose response of JNJ-77242113 at Week 16 in subjects with moderate-to-severe plaque psoriasis.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 February 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 35
Country: Number of subjects enrolled	Germany: 47
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Korea, Republic of: 11
Country: Number of subjects enrolled	Poland: 60
Country: Number of subjects enrolled	Taiwan: 13
Country: Number of subjects enrolled	United States: 50
Worldwide total number of subjects	255
EEA total number of subjects	123

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	236
From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 255 subjects were randomised and treated in the study. After Week 16 subjects who were not enrolled in long term extension (LTE) study (NCT05364554) were followed up for safety up to 4 weeks after the last dose of the study drug.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo tablets, 2 in the morning and 1 in the evening daily.

Arm title	JNJ-77242113 25 mg QD + Placebo

Arm description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 1 placebo tablet in the morning and 1 in the evening.

Investigational medicinal product name	JNJ-77242113
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-77242113 25 mg tablet once daily.

Arm title	JNJ-77242113 50 mg QD + Placebo

Arm description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 1 placebo tablet in the evening.

Investigational medicinal product name	JNJ-77242113
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-77242113 25 mg 2 tablets once daily.

Arm title	JNJ-77242113 25 mg BID + Placebo

Arm description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo tablet in the morning.

Investigational medicinal product name	JNJ-77242113
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-77242113 25 mg tablet twice daily.

Arm title	JNJ-77242113 100 mg QD + Placebo

Arm description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	JNJ-77242113
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-77242113 100 mg tablet once daily.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 1 placebo tablet in the morning and 1 in the evening.

Arm title	JNJ-77242113 100 mg BID + Placebo

Arm description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo tablet in the morning.

Investigational medicinal product name	JNJ-77242113
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-77242113 100 mg tablet twice daily.

Number of subjects in period 1	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo
Started	43	43	43
Completed	36	36	40
Not completed	7	7	3
Unspecified	-	2	-
Lost to follow-up	1	3	-
Withdrawal by subject	6	2	3

Number of subjects in period 1	JNJ-77242113 25 mg BID + Placebo	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo
Started	41	43	42

Completed	40	41	38
Not completed	1	2	4
Unspecified	-	1	1
Lost to follow-up	-	-	1
Withdrawal by subject	1	1	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.	
Reporting group title	JNJ-77242113 25 mg QD + Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.	
Reporting group title	JNJ-77242113 50 mg QD + Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.	
Reporting group title	JNJ-77242113 25 mg BID + Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.	
Reporting group title	JNJ-77242113 100 mg QD + Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.	
Reporting group title	JNJ-77242113 100 mg BID + Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.	

Reporting group values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo
Number of subjects	43	43	43
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	38	42	40
From 65 to 84 years	5	1	3
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	43.9	44.5	45.1
standard deviation	± 14.7	± 12.72	± 11.08

Title for Gender Units: subjects			
Female	18	11	16
Male	25	32	27

Reporting group values	JNJ-77242113 25 mg BID + Placebo	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo
Number of subjects	41	43	42
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	37	39	40
From 65 to 84 years	4	4	2
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	45.7	44.7	42
standard deviation	± 11.91	± 14.11	± 11.34
Title for Gender Units: subjects			
Female	11	11	12
Male	30	32	30

Reporting group values	Total		
Number of subjects	255		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	236		
From 65 to 84 years	19		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender Units: subjects			
Female	79		
Male	176		

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 25 mg QD + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 50 mg QD + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 25 mg BID + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 100 mg QD + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 100 mg BID + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Primary: Percentage of Subjects Who Achieved at Least 75 Percent (%) Improvement From Baseline in Psoriasis Area and Severity Index (PASI-75) at Week 16

End point title	Percentage of Subjects Who Achieved at Least 75 Percent (%) Improvement From Baseline in Psoriasis Area and Severity Index (PASI-75) at Week 16[1]

End point description:

Percentage of subjects who achieved PASI-75 score (greater than or equal to [>=] 75 percent [%] improvement from baseline in PASI) at Week 16 were reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. Full analysis set (FAS) included all randomised subjects who received at least 1 administration of study intervention.

End point type	Primary

End point timeframe:

Baseline, Week 16

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)	9.3	37.2	58.1	51.2

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	65.1	78.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Total Score at Week 16

End point title	Change From Baseline in PASI Total Score at Week 16

End point description:

Change from baseline in PASI total score at Week 16 was reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) referred to the number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	37	41	40
Units: Units on a scale				
arithmetic mean (standard deviation)	-3.59 (± 9.436)	-12.76 (± 8.050)	-14.56 (± 6.528)	-12.73 (± 8.021)

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	39		
Units: Units on a scale				
arithmetic mean (standard deviation)	-13.99 (± 8.653)	-17.44 (± 8.356)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 90% Improvement From Baseline in PASI (PASI-90) at Week 16

End point title	Percentage of Subjects Who Achieved at Least 90% Improvement From Baseline in PASI (PASI-90) at Week 16

End point description:

Percentage of subjects who achieved PASI-90 score (>=90% improvement from baseline in PASI) at Week 16 were reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. FAS included all randomised subjects who received at least 1 administration of study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)	2.3	25.6	51.2	26.8

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	46.5	59.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 100% Improvement From Baseline in PASI (PASI-100) at Week 16

End point title	Percentage of Subjects Who Achieved at Least 100% Improvement From Baseline in PASI (PASI-100) at Week 16

End point description:

Percentage of subjects who achieved PASI-100 score (>=100% improvement from baseline in PASI) at Week 16 were reported. The PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas was assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement from 0 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. FAS included all randomised subjects who received at least 1 administration of study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)	0	11.6	25.6	9.8

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				

number (not applicable)	23.3	40.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an Investigator Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16

End point title	Percentage of Subjects Who Achieved an Investigator Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16

End point description:

Percentage of subjects who achieved an IGA score of cleared (0) or minimal (1) at Week 16 was reported. The IGA documented the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions were graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)	11.6	39.5	58.1	51.2

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	62.8	64.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) at Week 16

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) at Week 16

End point description:

Percentage of subjects who achieved an IGA score of cleared (0) at Week 16 was reported. The IGA documented the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions were graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)	0	16.3	34.9	14.6

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	27.9	45.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Body Surface Area (BSA) at Week 16

End point title	Percent Change From Baseline in Body Surface Area (BSA) at Week 16

End point description:

BSA was commonly used measure of severity of skin disease. It was defined as the percentage of surface area of the body involved with the condition being assessed, (that is, plaque psoriasis). BSA was assessed using hand print method where the surface area of the subject's hand including the palm and all 5 digits was used as a guide to estimate 1% BSA. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	37	41	40
Units: Percent change				
arithmetic mean (standard deviation)	-2.4 (± 16.51)	-11.9 (± 10.00)	-15.3 (± 11.41)	-13.3 (± 11.08)

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	39		
Units: Percent change				
arithmetic mean (standard deviation)	-14.6 (± 14.03)	-21.0 (± 13.74)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores at Week 16

End point title	Change From Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores at Week 16

End point description:

Change from baseline in PSSD symptoms scores at Week 16 was reported. PSSD was a patient-reported outcome (PRO) questionnaire designed to measure severity of psoriasis symptoms and signs for the assessment of treatment benefit. PSSD was self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. Severity of each item was rated on 11-point numeric scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (least severe symptom) to 100 (most severe symptom) were derived. Higher score indicated more severe disease. FAS: all randomised subjects who received at least 1 administration of study intervention. 'N' (number of subjects analysed): number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	37	41	40
Units: Units on a scale				
arithmetic mean (standard deviation)	-0.8 (± 29.59)	-35.8 (± 29.22)	-36.7 (± 29.95)	-34.0 (± 29.19)

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	39		
Units: Units on a scale				
arithmetic mean (standard deviation)	-29.4 (± 28.28)	-44.0 (± 31.22)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PSSD Signs Score at Week 16

End point title	Change From Baseline in PSSD Signs Score at Week 16

End point description:

Change from baseline in PSSD sign scores at Week 16 was reported. PSSD was a PRO questionnaire designed to measure severity of psoriasis symptoms and signs for assessment of treatment benefit. PSSD was a self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. The severity of each item was rated on 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (least severe sign) to 100 (most severe sign) were derived. Higher score indicated more severe disease. FAS: all randomised subjects who received at least 1 administration of study intervention. 'N' (number of subjects analysed): number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	37	41	40
Units: Units on a scale				
arithmetic mean (standard deviation)	-6.2 (± 22.38)	-38.6 (± 27.55)	-42.7 (± 28.70)	-41.8 (± 27.78)

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	39		
Units: Units on a scale				
arithmetic mean (standard deviation)	-41.9 (± 28.65)	-51.1 (± 26.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PSSD Symptoms Score Equal to (=) 0 at Week 16 Among Subjects With a Baseline Symptoms Score Greater Than or Equal to (>=) 1

End point title	Percentage of Subjects Who Achieved PSSD Symptoms Score Equal to (=) 0 at Week 16 Among Subjects With a Baseline Symptoms Score Greater Than or Equal to (>=) 1

End point description:

The PSSD was a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs for the assessment of treatment benefit. PSSD was a self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. The severity of each item was rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (indicated least severe symptom) to 100 (indicated most severe symptom) were derived. A higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	42	41
Units: Percentage of subjects				
number (not applicable)	0	16.3	23.8	17.1

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	27.9	26.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PSSD Sign Score = 0 at Week 16 Among Subjects With a Baseline Sign Score >=1

End point title	Percentage of Subjects Who Achieved PSSD Sign Score = 0 at Week 16 Among Subjects With a Baseline Sign Score >=1

End point description:

The PSSD was a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs for the assessment of treatment benefit. PSSD was a self-administered PRO instrument that included 11 items covering symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding or flaking, redness and bleeding) using 0 to 10 numerical rating scales for severity. The severity of each item was rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). Two sub scores each ranging from 0 (indicated least severe sign) to 100 (indicated most severe sign) were derived. A higher score indicated more severe disease. FAS included all randomised subjects who received at least 1 administration of study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)	0	2.3	14.0	9.8

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	16.3	14.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved a Dermatological Life Quality Index (DLQI) of 0 or 1 at Week 16 Among Subjects With Baseline DLQI Score Greater Than (>) 1

End point title	Percentage of Subjects Who Achieved a Dermatological Life Quality Index (DLQI) of 0 or 1 at Week 16 Among Subjects With Baseline DLQI Score Greater Than (>) 1

End point description:

The DLQI was a dermatology specific health-related quality of life (HRQoL) instrument designed to assess the impact of the disease on a subject's HRQoL. It was a 10-item questionnaire that assesses HRQoL over the past week and in addition to evaluating overall HRQoL, could be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. Each question was scored on a 4-point scale of 0 to 3 (0 = not at all, 1 = a little; 2 = a lot; or 3 = very much, where higher score indicated more impact on QoL). The total score was sum of scores from all 10 questions and it ranged from 0 (not at all) to 30 (very much), with a higher score indicating greater impact on HRQoL. FAS included all randomised subjects who received at least 1 administration of study intervention. Here 'N' (number of subjects analysed) referred to the number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	43	43	40
Units: Percentage of subjects				
number (not applicable)	2.4	27.9	37.2	30.0

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	41		
Units: Percentage of subjects				
number (not applicable)	55.8	43.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Domain Scores of the Patient-Reported Outcomes Measurement Information System (PROMIS-29) at Week 16

End point title	Change From Baseline in Domain Scores of the Patient-Reported Outcomes Measurement Information System (PROMIS-29) at Week 16

End point description:

The PROMIS-29, a 29-item generic HRQoL survey, assesses each 7 PROMIS domains (depression; anxiety; physical function; pain interference; fatigue; sleep disturbance and ability to participate in social roles and activities) with 4 questions. The questions were ranked on 5-point Likert Scale (1=never, 2=rarely, 3=sometimes, 4=often and 5= always). Pain intensity was rated on 11-point scale (0=no pain; 10=worst imaginable pain). Norm-based scores have been calculated for each domain on PROMIS measures, score of 50 represents mean or average of reference population. Score of 60 means that person is one standard deviation above reference population. On symptom-oriented domains (anxiety, depression, fatigue, pain interference and sleep disturbance), higher scores represent worse symptomatology. On function-oriented domains (physical functioning and social role), higher scores represent better functioning. FAS was analysed. 'N'= number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	37	41	40
Units: Units on a scale				
arithmetic mean (standard deviation)				
Physical Function	-1.04 (± 5.929)	2.30 (± 6.060)	5.81 (± 6.896)	4.55 (± 7.789)
Anxiety	-2.36 (± 7.971)	-3.98 (± 8.789)	-5.27 (± 8.026)	-5.27 (± 6.787)
Depression	-1.01 (± 6.238)	-3.09 (± 8.709)	-3.23 (± 6.576)	-1.96 (± 6.569)
Fatigue	-0.76 (± 5.469)	-2.44 (± 10.983)	-1.50 (± 7.801)	-3.09 (± 8.676)
Sleep Disturbance	0.14 (± 6.099)	-1.89 (± 5.859)	-3.45 (± 7.947)	-4.36 (± 6.041)
Social Roles and Activities	0.99 (± 8.393)	4.31 (± 9.035)	4.82 (± 8.511)	5.39 (± 10.908)
Pain Interference	0.09 (± 7.819)	-6.79 (± 9.038)	-7.41 (± 9.867)	-7.18 (± 7.956)
Pain Intensity	0.7 (± 2.89)	-2.6 (± 2.94)	-2.7 (± 3.25)	-2.6 (± 3.25)

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	39		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Physical Function	3.10 (± 7.325)	5.81 (± 8.408)		
Anxiety	-4.70 (± 8.570)	-8.31 (± 9.693)		
Depression	-2.62 (± 7.465)	-3.67 (± 8.912)		
Fatigue	-2.98 (± 7.818)	-3.75 (± 8.409)		

Sleep Disturbance	-1.04 (± 5.995)	-3.19 (± 5.705)		
Social Roles and Activities	5.78 (± 7.538)	7.73 (± 9.607)		
Pain Interference	-3.98 (± 7.889)	-9.56 (± 8.668)		
Pain Intensity	-1.7 (± 3.00)	-3.3 (± 3.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least a 5-point Improvement From Baseline in Each PROMIS-29 Domain at Week 16

End point title	Percentage of Subjects Who Achieved at Least a 5-point Improvement From Baseline in Each PROMIS-29 Domain at Week 16

End point description:

PROMIS-29, 29-item generic HRQoL survey, assesses each 7 PROMIS domains (depression; anxiety; physical function; pain interference; fatigue; sleep disturbance and ability to participate in social roles and activities) with 4 questions. The questions were ranked on 5-point Likert Scale (1=never, 2=rarely, 3=sometimes, 4=often and 5= always). Pain intensity was rated on 11-point scale (0=no pain; 10=worst imaginable pain). Norm-based scores have been calculated for each domain on PROMIS measures, score of 50 represents mean or average of reference population. Score of 60 means that person is one standard deviation above reference population. On symptom-oriented domains (anxiety, depression, fatigue, pain interference and sleep disturbance), higher scores represent worse symptomatology. On function-oriented domains (physical functioning and social role), higher scores represent better functioning. FAS: all randomised subjects who received at least 1 administration of study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)				
Physical Function	11.6	23.3	41.9	36.6
Anxiety	30.2	32.6	44.2	53.7
Depression	23.3	27.9	34.9	26.8
Fatigue	18.6	20.9	23.3	41.5
Sleep Disturbance	16.3	23.3	32.6	43.9
Social Roles and Activities	23.3	30.2	46.5	56.1
Pain Interference	20.9	46.5	55.8	51.2

End point values	JNJ-77242113 100 mg QD +	JNJ-77242113 100 mg BID +		

	Placebo	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)				
Physical Function	37.2	40.5		
Anxiety	41.9	54.8		
Depression	32.6	35.7		
Fatigue	25.6	42.9		
Sleep Disturbance	23.3	38.1		
Social Roles and Activities	44.2	57.1		
Pain Interference	41.9	64.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Treatment-emergent Adverse Event (TEAEs) and Serious TEAEs

End point title	Percentage of Subjects With Treatment-emergent Adverse Event (TEAEs) and Serious TEAEs

End point description:

An AE was any untoward medical occurrence in a clinical investigation where subjects administered a product or medical device; the event needed not necessarily have a causal relationship with the treatment or usage. A SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, or resulted in congenital anomaly/birth defect. TEAE was defined as any event that occurs at or after the initial administration of study agent. The safety analyses set included all randomised subjects who received at least 1 administration of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to 4 weeks after last dose of study drug (up to 20 weeks)

End point values	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo	JNJ-77242113 25 mg BID + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	43	43	41
Units: Percentage of subjects				
number (not applicable)				
TEAEs	51.2	46.5	60.5	48.8
Serious TEAEs	0	0	2.3	0

End point values	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)				
TEAEs	44.2	61.9		
Serious TEAEs	4.7	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline (Week 0) up to 4 weeks after last dose of study drug (up to 20 weeks)

Adverse event reporting additional description:

The safety analyses set included all randomised subjects who received at least 1 administration of study intervention.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received 2 tablets of placebo matching to JNJ-77242113 in morning and 1 tablet in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in long term extension (LTE) study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 25 mg QD + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 milligrams (mg) once daily (QD) and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 100 mg BID + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg BID in morning and evening along with a matching placebo in morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 25 mg BID+ Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 25 mg twice daily (BID) in morning and evening along with a matching placebo in the morning to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 100 mg QD + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 100 mg QD and matching placebo in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Reporting group title	JNJ-77242113 50 mg QD + Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis received JNJ-77242113 50 mg QD (2*25 mg tablets) in morning followed by matching placebo in the evening to maintain the blind from Week 0 through Week 16. Subjects who were not enrolled in LTE study were followed up for safety up to 4 weeks after the last dose of the study drug.

Serious adverse events	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 43 (0.00%)	0 / 43 (0.00%)	0 / 42 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Psychiatric disorders			
Suicide Attempt			
subjects affected / exposed	0 / 43 (0.00%)	0 / 43 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Covid-19			
subjects affected / exposed	0 / 43 (0.00%)	0 / 43 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Cyst			
subjects affected / exposed	0 / 43 (0.00%)	0 / 43 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	JNJ-77242113 25 mg BID+ Placebo	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 41 (0.00%)	2 / 43 (4.65%)	1 / 43 (2.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Psychiatric disorders			
Suicide Attempt			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Covid-19			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Cyst			

subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	JNJ-77242113 25 mg QD + Placebo	JNJ-77242113 100 mg BID + Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 43 (23.26%)	10 / 43 (23.26%)	10 / 42 (23.81%)
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 43 (2.33%)	0 / 43 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 43 (2.33%)	2 / 43 (4.65%)	1 / 42 (2.38%)
occurrences (all)	1	2	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 43 (0.00%)	1 / 43 (2.33%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Infections and infestations			
Covid-19			
subjects affected / exposed	5 / 43 (11.63%)	5 / 43 (11.63%)	4 / 42 (9.52%)
occurrences (all)	5	5	4
Nasopharyngitis			
subjects affected / exposed	2 / 43 (4.65%)	1 / 43 (2.33%)	2 / 42 (4.76%)
occurrences (all)	2	1	3
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 43 (2.33%)	3 / 43 (6.98%)	2 / 42 (4.76%)
occurrences (all)	1	4	2

Non-serious adverse events	JNJ-77242113 25 mg BID+ Placebo	JNJ-77242113 100 mg QD + Placebo	JNJ-77242113 50 mg QD + Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 41 (29.27%)	8 / 43 (18.60%)	15 / 43 (34.88%)
Nervous system disorders			

Headache			
subjects affected / exposed	1 / 41 (2.44%)	3 / 43 (6.98%)	1 / 43 (2.33%)
occurrences (all)	2	3	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 41 (4.88%)	1 / 43 (2.33%)	4 / 43 (9.30%)
occurrences (all)	2	1	4
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 41 (0.00%)	3 / 43 (6.98%)	1 / 43 (2.33%)
occurrences (all)	0	3	1
Infections and infestations			
Covid-19			
subjects affected / exposed	8 / 41 (19.51%)	2 / 43 (4.65%)	3 / 43 (6.98%)
occurrences (all)	8	2	3
Nasopharyngitis			
subjects affected / exposed	3 / 41 (7.32%)	1 / 43 (2.33%)	8 / 43 (18.60%)
occurrences (all)	3	1	9
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 November 2021	The overall reason for the amendment was to clarify stratification and to clarify the contraceptive appendix.
12 January 2022	The overall reason for the amendment was to update the study intervention dosing instructions and to update the analysis strategy regarding discontinuations due to COVID-19 (intercurrent event number 3) to a Treatment Policy strategy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported